

REMARKS

The Office Action transmitted March 18, 2008 has been received and reviewed. All pending claims stand rejected. Reconsideration is respectfully requested.

The application is to be amended as previously set forth. All amendments are made without prejudice or disclaimer. Basis for the amendments to the claims to “more than 200 mg arginine” can be found, *inter alia*, in paragraph [0007] of the as-filed application (paragraph [0008] of the published application). Basis for the amendments to the claims 21 through 23 to “wherein the feed contains from 1.25 to 10 wt% arginine” can be found, *inter alia*, in claim 3. Basis for the amendment to claim 22 with respect to “wherein providing the feed to the gestating sow takes place during periods of placental angiogenesis and growth” can be found, *inter alia*, in claim 14. No new matter has been added.

Claims 1, 2, 7, 10, 11, 12, and 21 through 23 stand rejected as assertedly being obvious under 35 U.S.C. § 103 over Watanabe et al. Applicant respectfully traverses the rejection.

A framework for applying the statutory language of 35 U.S.C. §103 is set out in *Graham v. John Deere Co. of Kansas City*, 383 U. S. 1 (1966):

“Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.”

Id., at 17–18.

To establish a *prima facie* case of obviousness, the prior art itself or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the invention are to have taught or suggested the claim elements. Additionally, there is to have been “a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742, 167 L.Ed.2d 705, 75 USLW 4289, 82 USPQ2d 1385 (2007). “Often, it will be necessary for a [fact finder] to look to interrelated teachings of multiple patents; the effects of

demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed. . . . To facilitate review, this analysis should be made explicit.” *Id.* “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). Furthermore, to establish a *prima facie* case of obviousness, there must have been a reasonable expectation of success. M.P.E.P. § 2143.02. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 S.Ct. at 1742.

As provided for by the Office’s guidelines, in order to make an obviousness rejection such as that set forth in the Office action, the Office “must resolve the *Graham* factual inquiries”. *See, e.g., M.P.E.P.*, § 2143 A(1) (“Examples of Basic Requirements of a *Prima Facie* Case of Obviousness”). Contrary to these guidelines, however, the instant obviousness rejections never resolved what the level of ordinary skill in the pertinent art was at the time of the invention, which is required. *See, M.P.E.P.*, § 2141 II.

More substantively, amended claim 1 defines “an animal feed suitable for feeding a gestating animal and which improves the fertility of an animal fed said animal feed, which feed comprises an amount of lysine and the following amino acids in an amount relative to the amount of lysine (w/w) in the following ranges: total methionine + cysteine: >0.55; threonine: >0.60; tryptophan: >0.15; and arginine: >1.5, wherein a daily dosage of more than 200 mg arginine per kg body of the gestating animal (kgbw) is provided upon feeding.”

Specifically, Watanabe was thought to teach a feedstuff (the amino acid L- Tryptophan) for increasing performance of swine including increasing milk yield, reducing the recurrence days of estrus of dams, and decreasing the number of still births and premature pigs. Watanabe was further thought to teach “an embodiment that contains an assorted feedstuff of corn, soybean meal, bran and vitamin and mineral elements which has the particular amino acid breakdown of 1.07% arginine, 0.66% lysine, 0.50% methionine + cystine, 0.51 % threonine, and 0.16% tryptophan (Example 3). Said percentages can be translated into the following ratios relative to lysine: 1.62 arginine, 0.75 methionine + cystine, 0.77 threonine, and 0.24 tryptophan, which read

on all of the instant claimed ratios.” (*Office action*, page 2).

Applicant would respectfully point out, however, that Example 3 of Watanabe et al., specifically relates to increasing “milk yield” in twenty sows that evidently already had their “second delivery”, not to methods of increasing the breeding productivity of a gestating animal as is claimed in, e.g., claims 11 and 12. (*See, e.g.*, Watanabe et al., col. 5, lines 31-64).

Furthermore, the Office admits that Watanabe “is silent to the particular amount of arginine being at least 200 mg” as is claimed in the instant claims. However, the Office relies on applicant's statement that “[u]nder normal feeding conditions, this amounts to a daily dosage of about 65-200 mg arginine per kg body weight (kgbw) of the fed animal”, and the range of about 65-200 mg of arginine reads on the limitation ‘at least 200 mg arginine’ (*i.e.*, 200 mg or more) because they are considered overlapping ranges.” (*Office action*, pages 3-4).

To further distinguish the prior art, and as previously identified, applicant is amending the relevant independent claims to recite that the feed contains “more than” 200 mg arginine per kilogram body weight of the gestating animal, so the ranges are no longer overlapping.

One would not be motivated to add more arginine to Watanabe’s feed for various reasons. Among these reasons are cost (arginine is expensive) and in view of the previously discussed NRC standards which specifically state that pregnant swine already synthesize sufficient arginine so that supplementation is unnecessary. Sows synthesize arginine, and during post-pubertal growth and pregnancy, sows do so at a rate sufficient to meet their needs (*see, e.g.*, Easter et al., 1974; Easter and Baker, 1976). Thus, no reason would exist for one of ordinary skill in the art to supplement arginine in swine (let alone at “more than 200 mg arginine per kilogram body weight of the gestating animal” as required by the claims).

With specific respect to rejected claims 21 through 23, these claims are being amended to include the element of claim 3, “wherein the feed contains from 1.25 to 10 wt% arginine”. Claim 3 was not rejected as being obvious over Watanabe. Claims 21 through 23 (pre-amendment) were not rejected under the hereinafter described combination of Wilson et al. in view of Mahan and further in view of Kuroki. Accordingly, amended claims 21 through 23 should be patentable.

In view of the foregoing, applicant requests that the rejection based upon Watanabe et al. be withdrawn.

Claims 1 through 3 and 5 through 20 stand rejected as assertedly being obvious over Wilson et al. in view of Mahan and further in view of Kuroki. Applicant respectfully traverses the rejection.

Wilson teaches animal feed compositions and methods for increasing the reproductive performance of breeding populations of swine. Wilson's disclosure is however particularly directed to a method of increasing reproductive performance of female swine by administering ω -3-fatty acids to the swine, not selective amino acid supplementation as claimed in the instant application.

Wilson teaches incorporating ω -3-fatty acids into "any animal feed blend known in the art" including "rapeseed meal, cottonseed meal; soybean meal, and cornmeal". Such animal feed blends can include, as "optional amino acid ingredients", "arginine, histidine, isoleucine, leucine, lysine, methionine, threonine, tryptophan, valine, tyrosine ethyl HCl, alanine, aspartic acid, sodium glutamate, glycine, proline, serine, and cysteine ethyl HCl, and analogs." (Wilson, Paragraph 0031). No further mention of arginine is believed to be made in Wilson.

Wilson also teaches methods of administration ranging from feeding the composition to the animals daily for their lifetime, to feeding the composition to an animal before and/or during pregnancy and/or during lactation, and so on (paragraph 0030).

Wilson does not teach the specific amounts or selection of amino acids recited by applicant's claims or that they would have an effect, let alone a beneficial effect, on the breeding productivity of a gestating female. Furthermore, Wilson does not teach or suggest modifying the amount of arginine (or the lysine to arginine ratio) in Wilson's feed to levels claimed in the referenced patent application or any effect such a modification might have with respect to improving fertility. Wilson does not disclose the particularly claimed amounts of arginine (*e.g.*, "an animal feed suitable for feeding a gestating animal, which feed comprises an amount of lysine and [arginine] in an amount relative to the amount of lysine (w/w) [of] arginine >1.5, wherein a daily dosage of more than 200 mg arginine per kg body of the gestating animal (kg/bw) is provided upon feeding" as recited in amended claim 1 of the referenced patent application

Mahan teaches that soybean meal comprises amino acids including arginine, lysine, methionine, threonine, tryptophan, and cysteine and provides percentage amounts for each amino acid (Table 2). Table 2 teaches the following percentages: 3.56% arginine (which falls within the

claimed range of instant claim 3), 2.97% lysine, 0.65% methionine, 0.76% cysteine, 0.61 % tryptophan and 1.83% threonine. These percentages can be translated into ratios relative to the amount of lysine (*i.e.*, arginine = 1.2, methionine + cysteine = 0.47, tryptophan = 0.21, and threonine = 0.61). However, these digestibility trials were performed with barrows (*i.e.*, castrated male pigs) and not with pregnant animals. Mahan does not teach or suggest the relative amounts of amino acids claimed in the referenced patent application or the benefit of the amounts of amino acids on fertility.

Kuroki discloses a “method to artificially control gender” in cows comprising administering a particular “dense feed” 10 -14 days before ovulation.

Clearly, Kuroki should not detrimentally affect applicant’s “method” claims 11-19 and 22, which are, by their terms, directed to the administration of applicant’s feed to a gestating female. There is absolutely no teaching or suggestion found in the cited references directed to applicant’s method claims.

With respect to applicant’s composition claims (and summarizing), however, it is the Examiner’s position that

Kuroki teaches improving fertilization of cows by administering animal feed containing an additional 10g or more of arginine and 5g or more of lysine (pages 1 and 5). The ratio of arginine to lysine is approximately 2:1.

* * *

Wilson contains a generic teaching of an animal feed with additional amounts of amino acids for the ultimate goal of improving fertilization while Mahan teaches the natural composition of soybean meal and its intrinsic amino acid breakdown. Kuroki further provides motivation to include the particular amino acids, arginine and lysine in order to further improve fertilization. One of ordinary skill in the art would reasonably expect the combined teachings of Wilson, Mahan and Kuroki to produce an animal feed that improved fertilization. Also, it is well within the knowledge of a skilled artisan to further optimize the particular amounts of amino acids in the composition by way of routine experimentation. Thus in Wilson, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include additional amounts of arginine and lysine to animal feed, and if necessary, further optimize the animal feed composition in order to improve fertilization as suggested by Kuroki.

First, the proposed combination would not be made by one of ordinary skill in the art.

In all the examples shown by Wilson, the amount of soybean meal (44 sbm) is exactly the same in the control and treated groups, therefore the effects shown in the treated group are not readily attributable to arginine content of the soy bean meal

Besides, the diets supplied in Wilson contained not only soybean meal, but also contained corn (1396 lbs. in Example 2 and 1423 lbs. in Example 4). Following the National Research Council (NRC), a standard handbook reference for swine breeders, tables of composition of raw materials, corn grains contain 0.48% of arginine. Therefore, the amount of arginine in the final feed is 0.99% in Example 4 and 1.12% in Example 2. Furthermore, these diets were only administered until mating; during gestation, sows were “fed a common gestation ration until subsequent entry into the farrowing room”.

Also, the Office’s contention overlooks Wilson’s primary teaching, *i.e.*, that omega-3 fatty acids enhance fertility. Nothing in Wilson suggests or teaches modifying the arginine or other “optional” amino acid concentration of the feed to improve the fertility of an animal fed the animal feed.

Applicant further points out that a person of skill in the art would not have been motivated to increase the amount (or relative ratio) of arginine in a feed composition as the NRC states that swine during pregnancy synthesize all the necessary arginine. (Specification, page 3, lines 9-21 and as previously established in the prosecution hereof). According to this reference, excessive supplements of arginine are undesirable as they can reduce feed intake and reduce growth. As such, one of ordinary skill in the art would not have had a reasonable expectation of success by increasing the arginine content of the feed. This reference constitutes a “teaching away” from applicant’s invention. It certainly substantiates applicant’s assertion of “unexpected results”.

In conclusion, a *prima facie* case of obviousness has not been established because the cited references do not alone, or in combination, teach or suggest each and every element of any of claims 1-3 and 5-20. Moreover, applicant respectfully submits that one of ordinary skill in the art would not have been motivated to combine the cited references and, in light of the NRC text, one of ordinary skill in the art would have been taught away from combining the cited references. Therefore, it is requested that the rejection of the pending claims under 35 U.S.C. § 103(a) be withdrawn.

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The application should be in condition for allowance. If, however, questions remain after consideration of the foregoing, the Office is kindly requested to contact applicant's attorney at the address or telephone number given herein.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Allen C. Turner', with a horizontal line extending to the right.

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